News from the

U.S. Senate Committee on Health, Education, Labor and Pensions

Michael B. Enzi (Wyoming), Chairman



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CONGRESS APPROVES CONTACT LENS BILL TO PROTECT KIDS FROM EYE INJURY, INFECTION; GIVES FDA AUTHORITY TO REGULATE DECORATIVE LENSES; S. 172 AWAITS PRESIDENT'S SIGNATURE

Washington, D.C. - U.S. Senator Mike Enzi (R-WY), Chairman of the Senate Health, Education, Labor and Pensions Committee (HELP Committee), today said Congress has approved a bill to better protect children and adolescents from serious eye injury and infection by allowing the Food and Drug Administration (FDA) to regulate non-corrective lenses as medical devices.

The House gave unanimous approval to the bill, S. 172, last Wednesday. The Senate version, introduced by Senator Mike DeWine (R-OH), was approved unanimously by the Senate in July. It now awaits the President's signature.

Decorative and other non-corrective contact lenses, dispensed without a prescription or fitting from licensed professionals, have been linked to corneal ulcers and other eye problems, Enzi said. This is a health risk that needs our attention as thousands of kids head out to trick or treat today – many no doubt dressed in elaborate costumes that may include these unregulated products. So, I'm pleased that both the Senate and the House have now taken action to give the FDA greater authority to protect users of these products."

Enzi joined Senator DeWine, Congressman John Boozman (R-AR) and representatives from the American Optometric Association (AOA) today for a press conference to highlight the bill's final approval. Currently, the Food Drug and Cosmetic Act classifies non-corrective contact lenses as cosmetics, rather than as medical devices.

As a result, the FDA does not have adequate authority to ensure that all decorative lenses are safe. Moreover, because they are classified as cosmetics, decorative lenses are available to young people with little or no guidance on proper use to prevent infections or injuries.

Many manufacturers of non-corrective lenses voluntarily submit to FDA medical device regulation to assure eye care professionals that their products are safe and well-made, and I commend them for that," Enzi said. ABut the vast majority of the lenses that kids find in Halloween costume stores and novelty shops are not part of this voluntary program.

Enzi praised the strong support for the bill by Senator DeWine, the HELP Committee's Ranking Member, Senator Edward M. Kennedy (D-MA), Majority Leader Bill Frist (R-TN) and Congressman Boozman.

This is a simple but important bill that will protect kids from the dangers posed by unregulated, decorative contact lenses," he said.

